PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

FORTZAAR® Tablet

Losartan potassium and hydrochlorothiazide

Contains sugar:

Each tablet contains 126,26 mg of lactose hydrous.

Read all of this leaflet carefully before you start taking FORTZAAR

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- FORTZAAR has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What FORTZAAR is and what it is used for

FORTZAAR is a combination of the angiotensin II receptor antagonist (losartan) and a diuretic (hydrochlorothiazide). Losartan and hydrochlorothiazide work together to lower high

blood pressure.

Your doctor has prescribed FORTZAAR because you have a condition known as hypertension or high blood pressure.

2. What you need to know before you take FORTZAAR

Do not take FORTZAAR:

- if you are allergic to any of its ingredients (see section 6 What FORTZAAR contains).
- if you have previously been treated with a medication in the same group of medicines as FORTZAAR (angiotensin receptor antagonists) or with a medication in the group of medicines known as ACE inhibitors and have had allergic reactions with swelling of the face, lips, tongue and/or throat with difficulty in swallowing or breathing.
- if you have hereditary or idiopathic angioedema.
- if you have hypertrophic obstructive cardiomyopathy, a heart disorder in which the walls of the ventricles (lower heart chambers) thicken (hypertrophy) and become stiff and the thickened muscle blocks the flow of blood out of the heart.
- if you have severe kidney disease.
- if you have narrowing of the blood vessels to both kidneys or to a single kidney.
- if you have aortic stenosis, a narrowing of the aortic valve opening between the left ventricle (large pumping chamber of the heart) and the aorta (the main artery leading away from the heart).
- if you are taking diuretics (water pills) that cause your body to retain potassium such as spironolactone, triamterene and amiloride.
- if you have porphyria.
- Thiazide water tablets in fixed dose combination as with FORTZAAR, should not be given to patients with Addison's disease. This therapy should also not be used in patients with severe kidney disease or patients not passing urine, and in patients who

show allergy to other sulphonamide-derived medicines (ask your doctor if you are not sure what sulphonamide-derived medicines are).

- Lithium therapy: Concomitant administration with FORTZAAR may lead to toxic blood concentrations of lithium.
- if you are pregnant or are breastfeeding (see Pregnancy and breastfeeding).
- if you have liver disease.
- if you have diabetes or impaired kidney function and you are taking a medicine called aliskiren to reduce blood pressure.
- if you have moderate to severe kidney disease and are prescribed a course of an antibiotic of the fluoroquinolone class, for an infection. Ask your doctor what other drugs than FORTZAAR you should receive to control your blood pressure or if you should receive a different antibiotic.

Warnings and precautions

Take special care before taking FORTZAAR

- If you have or have had medical problems, any allergies, or if you have recently suffered from vomiting or diarrhoea.
- If you have any liver or kidney problems, gout, sugar diabetes, lupus erythematosus, or if you are being treated with diuretics (water tablets). In these cases, your doctor may need to adjust the dose of your medication.
- Taking a course of a fluoroquinolone antibiotic with FORTZAAR can cause acute kidney injury, especially if you have moderate to severe kidney disease, or you are elderly.
- Before surgery and any anaesthesia (even at a dentist’s office), tell the doctor or dentist that you are taking FORTZAAR, as there may be a sudden fall in blood pressure associated with the anaesthetic.
- If you are taking lithium (a medicine used to treat a certain kind of depression).

Tell your doctor if you are taking other medicines that may increase serum potassium (see Other medicines and FORTZAAR).

Tell your doctor if you have had skin cancer or if you develop a new skin lesion during the treatment. Treatment with hydrochlorothiazide, particularly long-term use with high doses, may increase the risk of some types of skin and lip cancer (non-melanoma skin cancer). Discuss with your doctor how to protect your skin from sun exposure, and avoid artificial tanning.

Children

As there is no experience with the use of FORTZAAR in children, FORTZAAR should not be given to children.

Use in the Elderly

FORTZAAR works equally well in and is equally well tolerated by most older and younger adult patients. Most older patients require the same dose as younger patients.

Other medicines and FORTZAAR

Always tell your healthcare provider if you are taking or planning to take any other medicine. (This includes complementary or traditional medicines.)

It is especially important for your doctor to know if you are taking potassium supplements, potassium-sparing medicines, salt substitutes containing potassium or other medicines that may increase serum potassium (e.g. trimethoprim-containing products), other medicines to reduce blood pressure, other diuretics (water tablets), medications to treat diabetes including insulin, resins which reduce high cholesterol, muscle relaxants, pressor amines such as adrenaline, steroids, certain pain and arthritis medicines or lithium (a medicine used to treat a certain kind of depression). Sedatives, tranquilisers, narcotics, alcohol and

analgesics may increase the blood pressure-lowering effect of FORTZAAR, so tell your doctor if you take any of these medicines.

Should your doctor prescribe an antibiotic medicine for an infection, tell your doctor that you are taking FORTZAAR.

FORTZAAR with food and drink

See section 3, How to take FORTZAAR for instructions on how to take FORTZAAR.

Pregnancy and breastfeeding

You should not use FORTZAAR while you are pregnant or breastfeeding your baby, as FORTZAAR may cause harm or death to an unborn baby. If you get pregnant while taking FORTZAAR, tell your doctor right away.

Women of childbearing age should ensure effective contraception while on FORTZAAR.

Tell your doctor if you are breastfeeding or are about to start breastfeeding. FORTZAAR is not recommended for mothers who are breastfeeding, and your doctor may choose another treatment for you if you wish to breastfeed.

If you are pregnant or breastfeeding your baby while taking FORTZAAR please consult your doctor, pharmacist or other healthcare professional for advice.

Driving and using machines

You should be careful in performing tasks which may require special attention (e.g. driving an automobile or operating dangerous machinery) until you know how you tolerate FORTZAAR.

It is not always possible to predict to what extent FORTZAAR may interfere with the daily activities of a patient. Patients should always ensure that they do not engage in the above activities until they are aware of the measure to which FORTZAAR affects them.

FORTZAAR contains lactose

FORTZAAR contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking FORTZAAR.

3. How to take FORTZAAR

Always take FORTZAAR every day, exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

It is important to continue taking FORTZAAR for as long as your doctor prescribes it in order to maintain smooth control of your blood pressure. Your doctor will tell you how long your treatment with FORTZAAR will last. Do not stop treatment early without consulting your doctor.

The usual dose of FORTZAAR is one tablet per day. Check with your doctor or pharmacist if you are not sure.

Taking FORTZAAR with food and drink

FORTZAAR can be taken with or without food. For convenience and to help you remember, try to take FORTZAAR at the same time each day.

Do not share FORTZAAR prescribed for you with others.

If you have the impression that the effect of FORTZAAR is too strong or too weak for you, tell your doctor or pharmacist.

If you take more FORTZAAR than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take FORTZAAR

Try to take FORTZAAR daily as prescribed. However, if you miss a dose, do not take an extra dose. Just resume your usual schedule.

4. Possible side effects

FORTZAAR can and does have side effects.

Not all side effects reported for FORTZAAR are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking FORTZAAR, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking FORTZAAR and tell your doctor immediately or go to the casualty department at your nearest hospital:

- a severe allergic reaction (rash, itching, swelling of the face, lips, mouth or throat that may cause difficulty in swallowing or breathing).

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to FORTZAAR. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following side effects which are seen frequently with FORTZAAR:

- weakness

- dizziness or light headedness due to a sudden drop in blood pressure when standing up quickly
- fatigue
- trouble sleeping
- headache
- fast heartbeat
- cough, inflammation of the throat, blocked nose
- nausea, vomiting, cramping, diarrhoea
- constipation
- back pain, muscle cramps
- your doctor may notice changes in the results of your liver function tests.

Tell your doctor if you notice any of the following side effects which are seen less frequently with FORTZAAR:

- your doctor may notice changes in the results of your blood tests
- eating disorders, raised blood sugar level, increased uric acid in the urine
- tingling sensation in the limbs, hands and feet
- your doctor may notice inflammation of your pancreas
- yellowing of the eyes or skin
- increased sensitivity of the skin to the sun.

Tell your doctor if you notice any of the following side effects which are seen with FORTZAAR – the frequency is unknown:

- taste alteration
- transient blurred vision
- urinating less often than usual
- not being able to perform sexually

- chest pain
- fever.

Hydrochlorothiazide, a component of this medicine, increases sensitivity of the skin to the sun and may increase the risk of some types of skin and lip cancer (non-melanoma skin cancer).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of FORTZAAR.

5. How to store FORTZAAR

- Store at or below 30 °C.
- Do not use this medicine after the month and year following EXP: on the container.
- Store all medicines out of reach of children.

Return all unused medicine to your pharmacist. Do not dispose of unused medicines in drains or the sewerage system (e.g. toilets).

6. Contents of the pack and other information

What FORTZAAR contains

The active substances are losartan potassium 100 mg and hydrochlorothiazide 25 mg per film-coated tablet.

The other ingredients are: carnauba wax, hydroxypropyl cellulose, microcrystalline cellulose, hypromellose, lactose hydrous, magnesium stearate, pregelatinised starch, quinolone yellow aluminium lake, titanium dioxide.

FORTZAAR contains lactose hydrous.

What FORTZAAR looks like and contents of the pack

FORTZAAR Tablets are light yellow, oval-shaped, film-coated tablets with “747” on one side and plain on the other side.

FORTZAAR Tablets are supplied in blister packs of 30.

Holder of Certificate of Registration

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